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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/335,032 05/16/99 VELOULESCU V 01107.78572

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HM12/0110

EXAMINER

MARTINELL, J

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

01/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/335,032	Applicant(s) VELCULESCU ET AL.	
	Examiner James Martinell	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 38-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 32-37, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 20) <input type="checkbox"/> Other: _____ |

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This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims 1-31 and 38-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 6.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-37, 43, and 44 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose or enable a specific patentable utility for the collections of probes claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

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and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-37, 43, and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims mention various NORF genes and probes that contain sequences contained within the NORF genes. Since the instant application does not disclose the sequences of the NORF genes, the application does not adequately disclose the invention in such manner that one of skill in the art would know what the invention is.

Claims 32-37, 43, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "comprises at least 14 contiguous nucleotides of a NORF gene comprising a SAGE tag as shown in SEQ ID NOs: 67-811" (claim 32) is vague, indefinite, and incomplete. The NORF genes themselves are not disclosed in the application, hence the sequences from which the 14 contiguous nucleotides are drawn are not adequately or completely disclosed. Any reference to essential subject matter made by incorporation by reference to any document other than an allowed U.S. Patent application or a U.S. Patent would be an improper incorporation by reference (see MPEP 601.01(p) A). Additionally, the claims are incomplete because the NORFs are referred to by SAGE tags to which they are attached, but no particular organism or genome is recited in the claims.

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- (b) The recitation of "NORF gene" (claims 32 and 33) is vague and indefinite because the metes and bounds of any particular NORF gene are not disclosed or set.
- (c) The recitation of "involved in" (claim 33) is vague and indefinite. The instant application does not disclose how to distinguish an involved gene from an uninvolved gene.
- (d) The recitation of "NORF No. 1, 2, 4, 5, 6, 17, 25, and 27" is vague, indefinite, and incomplete because the instant application does not disclose the structure of any one of the NORFs.
- (e) The recitation of "of distinct sequence" (claims 35, 36, and 37) is vague and indefinite because the instant application does not indicate from what each of the sequences are distinct. Additionally, the instant application does not distinguish a distinct sequence from an indistinct sequence.

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- (f) The recitation of "NORF genes" (claim 43) is vague and indefinite because the metes and bounds of any particular NORF gene are not disclosed or set.
- (g) The recitation of "comprises at least one probe comprising at least 14 contiguous nucleotides of each of the NORF genes identified by the SAGE tags shown in SEQ ID NOs: 67-811" is vague, indefinite, and incomplete. The NORF genes themselves are not disclosed in the application, hence the sequences from which the 14 contiguous nucleotides are drawn are not adequately or completely disclosed. Any reference to essential subject matter made by incorporation by reference to any document other than an allowed U.S. Patent application or a U.S. Patent would be an improper incorporation by reference (see MPEP 601.01(p) A). Additionally, the claims are incomplete because the NORFs are referred to by SAGE tags to which they

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are attached, but no particular organism or genome is recited in the claims.

(h) The recitation of "said probes" is incomplete because there is no antecedent basis for "said probes".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

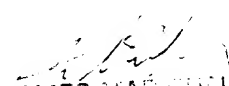
Claims 32-37, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goffeau et al (Science 274: 546 (1996)) in view of Velculescu et al (Science 270: 484 (1995)). Goffeau et al discloses the fact that the entire genome of *Saccharomyces cerevisiae* is known. Velculescu et al teaches the analysis of DNA by attaching DNA probes to a solid support. It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the DNAs of Goffeau et al to the solid support of Velculescu et al in order to analyze nucleic acid sequences in *Saccharomyces cerevisiae*.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1633 at (703) 308-4242. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

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Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.


JAMES MARTINELL, Ph.D.
SENIOR LEVEL EXAMINER